BRIEF IN SUPPORT THEREOF

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In the Supreme Court of the United States

OCTOBER TERM, 1942

RESEARCH LABORATORIES, INC.,
Petitioner,

vs.

UNITED STATES OF AMERICA,
Respondent.

BRIEF IN SUPPORT OF PETITION

STATEMENT

The statute under which jurisdiction is invoked in this case is Section 240, Judicial Code, 28 U.S.C.A., No. 347.

On the second day of June, 1941, the District Court of the United States for the Western District of Washington, Southern Division, entered an Order

sustaining Exceptions to the Amended Libel and an Order of Dismissal (R. 25).

On the 24th day of February, 1942, The United States Circuit Court of Appeals for the 9th Circuit filed and entered its Opinion containing an order for a decree to the effect that the said Order of the said District Court dismissing said Amended Libel was reversed (59-60).

On the 24th day of February, 1942, said United States Circuit Court of Appeals filed and entered a Judgment and Decree, based upon said Opinion, reversing the said Judgment and Order of The United States District Court for the Western District of Washington, Southern Division (66).

A Petition for Rehearing having been filed the said United States Circuit Court of Appeals for the Ninth Circuit on the 2nd day of April, 1942, made an Order denying said Petition for Rehearing (R. 67).

Thereafter, by order of the Honorable William O. Douglas, Associate Justice of the Supreme Court of the United States filed directly in said Court, the Petitioner was granted to and including the 1st day of August, 1942, within which to file a Petition for Writ of Certiorari to the said United States Circuit Court of Appeals.

STATEMENT OF FACTS

The case at bar is a proceeding in Admiralty brought by the United States of America against 143 Packages, More or Less, of a Product known as "Nue-Ovo", seeking the condemnation thereof as a drug within the meaning of Title 21, Sec. 321 (g) U.S.C. The Government alleged said drug to be misbranded in violation of the Federal Food, Drug & Cosmetic Act (21 U.S.C., Sec. 352 (a)). The case originated in the District Court of the United States for the Western District of Missouri, Western Division but such proceedings were had that it was afterward removed to the District Court of the United States for the Western District of Washington, Southern Division. The Petitioner, Research Laboratories, Inc., intervened and filed Exceptions to the Libel of Information, which Exceptions were upheld.

On December 7, 1940, the Government filed an Amended Libel of Information (R. 19) in which it was alleged that the goods seized and copies of the circulars which it was claimed constituted misbranding were shipped separately from Chicago, Illinois to Kansas City, Missouri, both consigned to the Crown Drug Company of the latter City. That the said circulars were received by said consignee simultaneously with the bottles of Nue-Ovo and that thereupon the Circulars and the said bottles were placed in the same room of the warehouse of

said Crown Drug Company in Kansas City and that thereafter in Kansas City the circulars and the packages of Nue-Ovo were sent together to certain retail drug stores of said company and that said circulars were prominently displayed in said retail stores in close proximity to the packages of Nue-Ovo and were distributed to members of the public who appeared in said drug stores. The Amended Libel alleged that the said circulars were false and misleading in that they create the impression in the mind of the reader that the article (Nue-Ovo) was a competent treatment for arthritis and that the use thereof would be beneficial in treating it, whereas in truth said article was not a competent and beneficial treatment for arthritis.

On the 18th day of December, 1940, the intervenor (the Petitioner here) filed its Exceptions to the Amended Libel of Information (R. 23). Exception No. III of these Exceptions to the Amended Libel charged that the same failed to state facts sufficient to constitute a cause of action.

In the said Amended Libel of Information a copy of the matter contained in each of the said circulars was set forth as an exhibit (R. 15-16). Throughout the proceedings there has been no contention by the Government that any of the said circulars was contained in the same package or packages of the said goods so seized, nor for that matter shipped together with the goods in the same

vehicle in interstate commerce. In other words, although the Government contends that the circulars "accompanied" said articles while in interstate commerce that claim is based upon the statement that the "circulars were received in interstate com-"merce by said Crown Drug Company at its ware-"house in Kansas City simultaneously with the bot-"tles of Nue-Ovo, the circulars and the bottles of "Nue-Ovo were placed in the same room of said ware-"house for distribution to three or more retail drug "stores of said drug company, the circulars and "packages of Nue-Ovo were sent together to the said "retail drug stores of said company and were promi-"nently displayed in said stores in the said rooms "and in close proximity to the packages of Nue-Ovo, "and were distributed to members of the public who "appeared in said drug stores."[1]

The Trial Court sustained the Exception that the Amended Libel fails to state facts sufficient to constitute a cause of action and dismissed the Government case, allowing the libelant an exception. Upon appeal to the United States Circuit Court of Appeals for the Ninth Circuit, the appellate Court rendered its opinion (R. 60) in which after stating the facts very much as stated above, it made, among others, the following observations pertinent to this case:

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[1] Quotation from page 3 of Government's Brief filed in United States Circuit Court of Appeals for the Ninth Circuit.

1. Thus, in substance, the libel states that 143 packages of Nue-Ovo and printed circulars containing false and misleading statements concerning Nue-Ovo were shipped in interstate commerce from Chicago, Illinois, to Kansas City, Missouri, and that all the packages and all the circulars were so shipped by a single shipper (Nue-Ovo, Inc.) to a single consignee (Crown Drug Company) and were by said consignee simultaneously received in interstate commerce.

2. These statements must, for present purposes, be taken as true. Taking them as true, we hold that the circulars accompanied the packages and constituted their labeling within the meaning of the Act; that, since the circulars were false and misleading, the packages were misbranded within the meaning of the Act; that, since the circulars accompanied the packages in interstate commerce, the packages were misbranded while in interstate commerce within the meaning of the Act; and that, therefore, the packages—and, of course, their contents—are subject to condemnation.

3. The libel does not state, nor is it material, whether the packages and the circulars did or did not travel in the same crate, carton or other container or on the same train, truck or other vehicle during their interstate journey. The packages and the circulars had a common origin and a common destination and arrived at their destination simul-

taneously. Clearly, therefore, they accompanied each other, regardless of whether, physically, they were together or apart during their journey.

4. Appellee contends that the circulars constituted advertising and, therefore, did not constitute labeling within the meaning of the Act. The contention assumes that printed matter (such as circular) cannot constitute both advertising and labeling. The assumption is unwarranted. Most, if not all, labeling is advertising. The term "labeling" is defined in the Act as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.

5. The rule of strict construction invoked by appellee has little or no application to statutes designed, as the Federal Food, Drug and Cosmetic Act is designed, to prevent injury to the public health. A. O. Andersen & Co. v. United States, 9 Cir. 284 F. 542, 543; United States v. 48 Dozen Packages of Gauze, 2 Cir., 94 F. (2d) 641, 642.

6. It is immaterial, if true, that the makers and advertisers of Nue-Ovo could have been proceeded against by the Federal Trade Commission under the Federal Trade Commission Act and could have been ordered to cease and desist from publishing and distributing the circular entitled "What is Arthritis." The power of the District Court to condemn misbranded articles is not impaired, dimin-

ished, or in any wise affected by the possibility that such misbranding may also be the subject of a cease and desist order or even by the fact, if it be a fact, that such an order has actually issued.

7. There is no merit in appellee's contention that the libel does not sufficiently charge that the circular entitled "What is Arthritis" is false and misleading. The circular states, in substance and effect, that Nue-Ovo is a competent and beneficial treatment for arthritis. The libel charges that it is not, and that, therefore, the circular is false and misleading. No other charge is necessary.

SPECIFICATIONS OF ERRORS

1. TheAppellate Court erred in holding that under the facts as stated, the circulars accompanied the packages and constituted their labeling within the meaning of Sec. 201 (m) of the Act, 21 U.S.C.A. No. 321 (m).

2. The Appellate Court erred in holding that it was immaterial whether the packages and the circulars did or did not travel in the same crate, carton or other container or on the same train, truck or other vehicle during their interstate journey.

3. The Appellate Court erred in holding that Circulars not contained in or on the package containing the goods constituted labeling within the meaning of the Act.

ARGUMENT

This case is one of first impression. The provisions of section 201 (m) of the Federal Food, Drug, and Cosmetic Act here involved (21 U.S.C., sec. 321 (m)) have not heretfore been construed by any Appellate Court.

It is believed that the decision of the appellate court holding that the circulars accompanied the packages and constituted their labeling within the meaning of the act is based on a premise demonstrably false.

It is believed further that the effect of a proceeding before the Federal Trade Commission which has become final, based on the same circulars involved in an action instituted under the authority of the Food and Drug Act, has been decided without due consideration of the doctrine of *res judicata.*

The Food and Drug Act and the Federal Trade Commission Act touch the interest of the business of the country to an extent which admits of no exaggeration. The importance of sound judicial construction of the provisions of those acts needs only be stated to be proved.

Because of these facts, the case is worthy of further attention, to the end that matters bearing on the intent of Congress in the enactment of the statute in question may be considered and given their proper place in the judgment which this court shall finally

pronounce, and to the further end that a conflict of jurisdiction as between the Food and Drug Administration and the Federal Trade Commission, which Congress was careful to avoid, be not created by judicial construction.

The Proper Construction of the Section of the Food and Drug Act Here Involved.

A proper construction of the phrase "accompanying such article" as contained in the definition of the word "labeling" requires that the phrase be held to mean that circulars, booklets or pamphlets accompany the article in question only when they are contained *on* or *in* the article or package; that, if they are merely in proximity, close or remote, to the article, they do not accompany the article *in the statutory sense of the phrase.* They are then advertising within the statutory definition of that word as contained in the Federal Trade Commission Act.[2]

We do not wish to be understood as being of the opinion that a given circular, booklet or pamphlet cannot be both labeling and advertising at one and the same time in the sense in which those words are commonly and generally understood. Our position is that booklets, circulars and pamphlets, while a species of advertising in the commonly accepted under-

2 Section 15 (U.S.C.A. sec. 55): "For the purposes of sections 12, 13 and 14—a. The term 'false advertisement' means an advertisement *other than labeling,* which is misleading in a material respect * * *."

standing of the word, acquire the *statutory* status of *labeling* only if they are *on* or *in* the article or its package. If separate and apart from the article and its package, such media of advertising are beyond the scope of the Food and Drug Act, do not "accompany" the article *in the statutory sense of the term*, remain only advertising as such, are therefore within the provisions of the Federal Trade Act, and cannot by virtue of the statutory definition itself be labeling. Whatever significance may be commonly accorded these words, under the definition of advertising contained in the Trade Act, that which is labeling cannot be advertising, and, conversely, if the media is such as to properly constitute advertising under the Trade Act, *the idea of labeling is statutorily excluded.*

The history of the two acts, judicial construction, construction by the Federal Trade Commission, and the source of the very phrase "accompanying such article" demonstrate the fact:

The History of the Acts

The Food and Drug Act as first enacted, insofar as it pertained to labels, was held to apply only to matter physically *on* the article and not applicable to advertising media contained *within* the package. (*U. S. v. American Druggists Syndicate*, 186 Fed. 387.)

The cited case was decided in 1911. To meet the defect in the act pointed out in that decision, the act was amended in 1912 and extended to include matter contained *in the article or its package.* (*Seven Cases v. U. S.*, 239 U.S. 510, 60 Lawyers' Ed. 411.)

All during this time advertising was within the scope of the Federal Trade Act, and false and misleading advertisements were controlled under or by virtue of that act, this not because of express control conferred in the act, but because advertising was judicially considered to be an unfair method of competition, well within the organic law of the Federal Trade Commission (*Federal Trade Commission v. Winstead Hosiery Co.*, 258 U.S. 483, and *Royal Baking Powder Co. v. Federal Trade Commission*, 281 Fed. (C.C.A. 2nd) 744.)

Efforts were made in Congress to so amend the Food and Drug Act as to bring within it control over false advertising.[3]

All of the acts which were introduced with this object in view failed passage because of the attempt to transfer control of false advertising from the Trade Commission to the Food and Drug Administration.[4]

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3 S. 1944, 73rd Congress, 1st and 2nd Sessions.
S. 2000, 73rd Congress, 2nd Session.
S. 2800, 73rd Congress, 2nd Session.
S. 5, 74th Congress, 4th Session.
S. 5, 75th Congress, 1st and 2nd Sessions.

4 74th Congress, 2nd Session, Cong. Rec., pp. 10, 514.

Each bill introduced for the purpose of conferring on the Food and Drug Administration jurisdiction over advertising defines the term "label" as meaning the principal labels (1) *upon* the immediate container and (2) *upon* the outside container of the article. They define the term "labeling" as including all labels and other written, printed and graphic matter *in any form whatsoever* accompanying the article.[5] They further define the term "advertisement" as including all representations of fact or opinion, disseminated in any manner or by any means *other than by the labeling.*

As finally enacted, the definition accorded to the term "label" was amended to include only matter *upon* the immediate container. The definition of "labeling" was changed to embrace only matter *upon* the article or any of its containers or wrappers or *accompanying such article.* As finally enacted, the all-embracive definition of labeling contained in the various bills refused passage, which would have included written, printed and graphic matter *in any form whatsoever* accompanying the article, *was omitted,* as were all provisions which defined the term "advertisement".

At the same session of Congress at which the Food and Drug Act as it now reads was finally passed, amendments to the Federal Trade Commission Act were adopted for the express purpose of giving more effective and necessary control over

[5] See Brief of Appellant, pages 12-13.

false advertisements of food, drugs, devices and cosmetics to the Federal Trade Commission.[6]

It will be observed that the phrase "accompanying the article", as it appears in the present law, appeared in substance in each of the bills which had for their object the enlargement of the jurisdiction of the Food and Drug Act so as to embrace false advertising. The words in these various bills were "accompanying any food, drug, or cosmetic". We are not without light as to the meaning in which this was understood by Congress. Senator Copeland, who fathered the various bills through the several sessions of Congress in which the amendments were considered, speaking to section 6 (a) of the first bill introduced by him for the purpose (S. 1494, 73rd Congress, 1st Session), the section which dealt with labeling, in comparing the bill with the then existing law, stated that the bill as presented covered cosmetics, as to which there was no provision in the old law, but that otherwise the proposed law was essentially the same as the old.[7]

At the second session of the same Congress, Senator Stephens read the report[8] of Senator Copeland's Committee on Interstate and Foreign Commerce concerning the same bill, and in connection with the significance to be accorded to the definition of labeling had this to say:

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6 House Report No. 163, 1st Session, 75th Congress. House Report No. 1613, 1st Session, 75th Congress.

7 73rd Congress, 1st Session, Cong. Rec. p. 5721.

8 S. Rep. 493, 2nd Session, 73rd Congress.

"Paragraph (h) defines label as the principal label on the immediate container and on the outside of the retail package, and paragraph (i) defines labeling as including labels and all other written, printed or graphic matter accompanying the article. *This differentiation* between label and labeling *is necessary because* the declaration of certain facts for the information and guidance of consumers required *on* the label by the substantive provisions of this bill should, to accomplish their purpose, appear on the principal label or labels where they can be easily observed, rather than in side panels of the labeling *or in circulars WITHIN the package where they may appear* * * *"

Further speaking to section 6 of the proposed bill, the Senator said:

"Section 6 is a general misbranding paragraph applicable to all products covered by the bill. Paragraph (a) holds these products misbranded if their labeling is false or misleading in any particular. This language is in the misbranding provisions of the present law, and has been fully interpreted by the United States Supreme Court."

When Senate 5 was before the first session of the 75th Congress in 1937, the committee report on the bill clearly disclosed the distinction that was drawn between advertising and labeling. The report[9] in this connection reads as follows:

"There has been controversy as to whether the Food and Drug Administration or the Federal Trade Commission should enforce the bill's provisions on advertising. *On the premise* that

[9] Report No. 152, Senate Committee in Congress, 1st Session, 75th Congress, February 15, 1937.

> ***advertisements*** of foods, drugs, and cosmetics *are nothing more than extensions of the labeling,* this bill proposes that the control be vested in the Food and Drug Administration which enforces the provisions on adulteration and labeling. But, it does not have the effect of depriving the Federal Trade Commission of its jurisdiction to proceed against false advertising in such form as to make it an unfair method of competition. The bill specifically provides that it shall not be construed as impairing or diminishing the powers of the Federal Trade Commission."

It is, we believe, clear beyond doubt that when these various bills were before Congress the phrase "accompanying the article", as contained in the definition of labeling, was intended by the author of the bills and was understood by Congress to mean only such matter, circulars, booklets, pamphlets or similar media as was contained *within* the package; that matter not within the package was understood to be beyond the scope of the definition accorded to the word "labeling"; was embraced within the definition of advertising under the Federal Trade Commission Act; and jurisdiction over such matter specifically refused to the Food and Drug Administration and specifically continued with the Federal Trade Commission.

For emphasis we repeat that the statutory definition of the word "labeling" shows no serious de-

parture, if any, from its well established meaning. Sec. 321 (m), Title 21, U.S.C. defines it:

> "The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

Subsection (1) adheres rigidly to the orthodox concept by which the labeling is affixed to the article itself or to the paper or substance which is its dress.

Subsection (2) was no doubt enacted to cover the common practice of manufacturers' inserting small circulars containing directions for usage, etc. in the carton which, strictly speaking, are not attached to the article but which nonetheless accompany, the article into the homes of the consumers.

The essential factor, *that labeling always goes with the product*, is preserved by the statutory definition. This factor, it is submitted, distinguishes "labeling" from "advertising". In defining "labeling" the Congress was plainly dealing with printed matter that appears on each bottle or container or is wrapped or packed with each bottle or container and hence is delivered to the consumer with each and every purchase.

In view of the fact that Congress decided that evils in the field of advertising as to food, drugs, and cosmetics were to be handled by the Federal Trade Commission, and the Copeland Bill was there-

fore amended accordingly, there is no justification for any court to put a strained and unnatural construction upon the term "labeling". Furthermore, the Food and Drug Act is a criminal statute. In *United States v. Weitzel*, 246 U.S. 533, the Supreme Court stated (p. 543):

> ". . . . Statutes creating and defining crimes are not to be extended by intendment because the court thinks the legislature should have made them more comprehensive. . . ."

To the same effect, see *Walter W. Oeflein, Inc. v. The State*, 177 Wis. 394, 395.

Judicial Construction and Source of the Phrase

The old law, prior to the 1938 amendments, provided, as we have seen, that labeling included only such matter as was *on* or *in* the article or its package. The law, as it presently reads, changes the phraseology of the definition, *but does not change its sense.*

The Food and Drug Administration understood the old law to mean that control was afforded under it over statements concerning a product that *accompanied* the package in the form of circulars.[10]

All who had to do with these various bills had a common understanding of the definition of labeling

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10 Testimony of Walter G. Campbell, Chief of the Food and Drug Administration, before a subcommittee of the Senate Committee on Commerce. Dec. 7-8, 1933. 73rd Congress, 2nd Session. (R. 16.)

as contained in the old law and the proposed amendments. We have seen that this understanding was that the definition of "labeling" under the old law, as including matter on or in the package, *was synonymous* with "accompanying the package".

The source of their understanding of these definitions as synonymous is readily available. The Supreme Court of the United States had recently decided the case of *Seven Cases v. U. S.*, supra. The Attorney General, in presenting the case for the United States, first used the terms synonymously.[11] Justice Hughes, in writing the opinion for the court, followed the arguments of the Attorney General and in his opinion *used the very words* which now appear in the statute and which are the subject of the discussion here. He there says:[12]

> "It appears from the legislative history of the act that the word 'contained' was inserted in the amendments to hit precisely the case of circulars or printed matter placed *inside* the package, and we think that is the only import of the provision * * * and the power of Congress manifestly does not depend upon the mere location of the statement *accompanying the article*, that is, upon the question *whether the statement is on or in the package* which is transported in interstate commerce."

Repeatedly throughout this opinion Justice Hughes used these terms as interchangeable. For instance, in considering the phrase "false and fraudulent", he says:

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11 See case as reported in 60 Lawyers' Ed., p. 413.
12 60 Lawyers' Ed. 416.

> "This phrase must be taken with its accepted legal meaning, and thus it must be found that
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> the statement *contained in the package* was put there to *accompany the goods*, with the actual intent to deceive * * *."

This case was considered by the House Committee, which considered and reported the bill which in 1938 became the law as it appears in the books today.[13]

Here, we believe, is the source of the phrase "accompanying such article" as it appears in the section of the law on the interpretation of which this case hinges, and here also is the meaning which that phrase must be accorded. As used by Justice Hughes and as understood by Congress, the phrase means that written, printed or graphic matter cannot be said to *accompany* an article within the sense of the statute unless such matter is *on* or *in* the article or its package. While it is undoubtedly true, *generally speaking*, that circulars, booklets or pamphlets accompany an article when shipped together, although in separate packages, it would be legislation by judicial construction to hold that such matter accompanies an article, *within the statutory significance* accorded to this term in the Food and Drug Act, unless the matter itself is a part of the package, that is, where the matter is on or in the article or its container. Furthermore, it is not true, *generally speak-*

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[13] Rep. No. 2139, House Committee on Interstate and Foreign Commerce, 3rd Session, 75th Congress, Apr. 14, 1938.

ing, that circulars could be said to accompany an *article* when the two are shipped in separate containers traveling in different trains, trucks, or other vehicles.

Construction by Federal Trade Commission

As we have seen, the jurisdiction of the Federal Trade Commission over advertising expressly excludes such matter as comes within the statutory connotation of labeling. This court has quite recently upheld a cease and desist order entered by the Federal Trade Commission on a showing that booklets and pamphlets, together with other media, contained false and misleading statements. (*Alberty v. Federal Trade Commission,* 118 Fed. (2d) 669.)

Summary

In view of the foregoing, we believe that, unless it appears that circulars, booklets and pamphlets are *in* the package or its containers, they cannot be said to accompany the article so as to constitute labeling within the meaning of the act.

The Effect That Should Be Given to a Final Order of the Federal Trade Commission Based on the Same Facts.

The court has here decided that it is immaterial that a cease and desist order might be or has been issued by the Federal Trade Commission.

It is felt that the court has failed to give proper effect to the doctrine of *res judicata* in this conection. If it be the fact that a cease and desist order was granted or was denied based on the same advertising matter that is made the basis of the libel, the issue as to whether the circulars were false and misleading, also as to whether they were advertising or labeling necessarily would be foreclosed in this proceeding based on the Food and Drug Act, by virtue of the doctrine of *res judicata.* This is so for the reason that a finding by the Trade Commission that the circulars constitute advertising necessarily negatived the possibility that they were labeling. False advertising, as defined in the Federal Trade Act, means an advertisement other than labeling.[14]

Under familiar rules (*Cromwell v. County of Sac,* 94 U.S. 351, 352) the finding by the Federal Trade Commission on this issue when it has become final operates as an estoppel against the right of the Government to assert the contrary in a proceeding under the Food and Drug Act.

We do not desire to be understood as contending that a cease and desist order directed against the circulars in question would, under any and every circumstance, have this effect. If the circulars proceeded against before the Trade Commission were entirely separate and apart from the articles to

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14 Sec. 15, Fed. Trade Com., 15 U.S.C.A., Sec. 55.

which they related, a finding that they were advertising would of course be sound. Where, however, the finding was based on facts which showed that the order was issued against the circulars because of their proximity to the article in question, where they accompanied the article, in the *commonly* accepted understanding of that term, the negation of labeling necessarily implied in the finding of advertising would preclude a later finding of labeling on the same facts.

CONCLUSION

In conclusion we respectfully suggest that for the reasons herein stated the decision of the Appellate Court is unsound; that it should be held that a circular recommending a product is purely advertising, unless it is inserted with the article in a common cover. Certain it is, that there is no showing that a circular of advertising matter accompanies the advertised article in interstate commerce, unless it be shown that it crosses a state border in the same train, truck or other vehicle with the advertised article.

We also respectfully suggest that the importance of the issues of law here involved as they affect many persons engaged in the business of manufacturing drugs, food products and cosmetics is such as to justify and require a decision and determination of

this question by the Supreme Court of the United States.

Respectfully submitted,
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